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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MERTZ, PREMA MARIA

ART UNIT PAPER NUMBER

1646

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,841

Applicant(s)

GRABSTEIN ET AL.

Examiner

Prema M. Mertz

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/15/06
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-30, 34, 35 and 41-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-30, 34-35, 41-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amended claims 20, 41 (5/15/06) and previous claims 21-30, 34-35, 42-45 are pending and under consideration by the Examiner.

2. The following previous objections and rejections are withdrawn in light of applicants arguments filed on 5/15/2006:

(i) the rejection of claims 41-45 under 35 USC 112, first paragraph, for lack of adequate written description. Applicant's arguments with respect to claims 41-45 have been considered but are moot in view of the new ground(s) of rejection for the recitation of "specifically forming a stable duplex".

(ii) the rejection of claims 41-45 under 35 USC 112, second paragraph. Applicant's arguments with respect to claims 20-30, 34-35 have been considered but are moot in view of the pending ground(s) of rejection over these claims.

3. Applicant's arguments filed on 5/15/2006 have been fully considered and were persuasive in part. The issues remaining and new issues are stated below.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-35 USC § 112, first paragraph, written description rejection

5. Claims 41-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which has not been described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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This rejection is maintained for reasons of record set forth at pages 3-6 of the previous Office action (8/9/2004) and pages 2-4 of the previous Office action (3/2/2006).

Applicants argue that claim 41 has been amended to recite “specifically forming a stable duplex”. However, contrary to Applicants arguments, the claims encompass a set of sequences, which has the function of forming a stable duplex. There are unlimited number of oligonucleotide molecules that form the genus of oligonucleotide molecules encompassed by the claim. The recitation of “at least 14 nucleotides” encompasses oligonucleotides that are larger than 14 nucleotides and Applicants have failed to provide a written description of which oligonucleotides can form a stable duplex. The functional language in the claim i.e. “encodes a polypeptide comprising SEQ ID NO:3 or SEQ ID NO:6” is not with respect to the claimed oligonucleotide but with respect to the nucleic acid to which the claimed oligonucleotide forms a stable duplex with. There is no functional language together with structural language recited in the claim. The only language recited for the claimed oligonucleotide is that it can form a “stable duplex”. Therefore, Applicants have not provided written description in the specification for claims drawn to a genus of oligonucleotides that is defined only by “specifically forming a stable duplex”. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics of the oligonucleotide, the specification does not provide adequate written description of the claimed genus of oligonucleotides.

Claim rejections-35 USC § 112, second paragraph

6. Claims 20-30, 34-35, are rejected under 35 U.S.C. 112, second paragraph.

This rejection is maintained for reasons of record set forth at page 6 of the previous Office action (8/9/2004) and pages 4-5 of the previous Office action (3/2/2006).

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Claim 20(c)-(d), lines 3-4, are rejected as vague and indefinite for the recitation of "...12 contiguous nucleotides complementary to...", which encompasses fragments of the complement of SEQ ID NO:1 and 4 since the claim does not recite how many nucleotides there are in the complement or the length of the complement or the upper limit of the nucleotides in the complement. Furthermore, it is unclear whether the claimed nucleic acid of claim 20(c)-(d) is composed of complementary as well as non-complementary sequences of SEQ ID NO:1 or 4. In addition, this limitation encompasses any piece of nucleic acid that is the complement of SEQ ID NO:1 or 4 that is at least 12 contiguous nucleotides or 12 contiguous nucleotides attached to totally unrelated nucleotides. This rejection can only be obviated by reciting "a nucleic acid of at least 12 contiguous nucleotides which is the full complement of SEQ ID NO:1 or 4".

Claims 30, 34-35 are rejected as vague and indefinite insofar as they depend on claim 20 for its limitations.

Claim rejections-35 USC § 102

7. Claims 20, 26, 30, 34, 35, are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. (1991).

This rejection is maintained for reasons of record set forth at page 7 of the previous Office action (8/9/2004), pages 4-5 of the previous Office action (3/31/2004) and pages 6-7 of the previous Office action (3/2/2006).

Applicants argue that there is no evidence that the oligonucleotide of Smith comprising the sequence ATGAGAATTTCGA would specifically bind to a polynucleotide of SEQ ID NO:1 or 4 or the complements thereof. Furthermore, Applicants argue that the Smith ATGAGAATTTCGA sequence is not isolated. However, contrary to Applicants arguments,

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Applicants have provided no evidence that the identical 12 nucleotides in common in the Smith reference will not specifically bind to the complement of SEQ ID NO:1. Those of skill in the art would expect the specific binding of the 100% identical nucleotides 1-13 of SEQ ID NO:1 and ATGAGAATTTCTGA of the reference. The prior art nucleic acid would inherently have the capability of specifically binding to the polynucleotide of SEQ ID NO:1. There is enough complementarity for the prior art nucleic acid to specifically bind to the polynucleotide of SEQ ID NO:1 under the right conditions. Applicants are again reminded that “Argument of counsel cannot take the place of evidence lacking in the record” (*In re Scarbrough*, 182 USPQ 298, 302 (CCPA 1974)).

With respect to Applicants argument that the Smith ATGAGAATTTCTGA sequence is not isolated, claim 20 recites “an isolated nucleic acid.....of at least 12 contiguous nucleotides....”. However, contrary to Applicants argument, the claim does not recite “an isolated nucleic acid.....consisting of 12 contiguous nucleotides....”. Even though the reference teaches a polynucleotide of over 592 nucleotides the claim recites “an isolated nucleic acid..... of at least 12 nucleotides” which limitation encompasses a 12-mer within a larger sequence. Furthermore, Applicants are arguing the limitation of “forming a stable duplex” when such is not recited in the claim. Applicants are absolutely right, Smith does not teach an isolated oligonucleotide ATGAGAATTTCTGA but neither does the claim recite such.

Furthermore, Applicants argue that Smith represents a different protein art (cellular retinol binding protein) and one of skill in the art would not look to a cellular retinol binding protein for teaching of an oligonucleotide capable of specifically binding to IL-15. However, contrary to Applicants arguments, the claim does not recite that the oligonucleotide of the claim

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cannot be one that encodes a cellular retinol binding protein and must encode IL-15. The Smith reference clearly anticipates claims because it is an isolated nucleic acid of at least 12 nucleotides of SEQ ID NO:1. Furthermore, in the absence of the recitation of “fully complementary to SEQ ID NO:1”, the nucleic acid of the reference would specifically bind to the polynucleotide of SEQ ID NO:1 and the Smith polynucleotide satisfies the language of “an isolated nucleic acid...at least 12 contiguous nucleotides of SEQ ID NO:1”.

Therefore, the prior art anticipates claims 20, 26, 30, 34-35.

Conclusion

No claim is allowed.

Claims 20-30, 34-35, 41-45 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
June 29, 2006